Remarks

Reconsideration of this Application is respectfully requested.

Claims 45-47, 49-59, 61-82 and 85-91 are pending in the application, with claims 45, 46, 58, 59, 72, 85 and 91 being the independent claims.

Based on the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding objections and rejections and that they be withdrawn.

I. Oath/Declaration

The Examiner stated that the present Oath/Declaration remains defective for the reasons made of record in the Office Actions mailed on April 12, 1999 (Paper No. 2) and September 22, 1999 (Paper No. 8). (*See* Paper No. 33, page 2.) Applicants respectfully submit that the reasons for finding the Declaration defective, as set forth in Paper No. 2, are in error. Therefore, the objection to the Declaration should be withdrawn.

According to the first Office Action:

> The oath filed on 25 July 1997 in the parent application (of which the instant application is a Continuation filed under 35 U.S.C. § 120) indicates on the first page that "the specification is attached hereto unless the following box is checked. . .". The box is not checked, so the oath refers to a specification which would be "attached hereto." This would be incorrect. A corrected oath is needed.

(Paper No.2, page 8.) Applicants respectfully submit that no correction to the Declaration is needed.

An Applicant is not required to submit a newly executed declaration in a continuation application as long as: (i) the prior nonprovisional application contained a valid oath or declaration (*i.e.*, in compliance with the requirements of 37 C.F.R. § 1.63(a)-(c)); (ii) the continuation application was filed by all or by fewer than all of the inventors named in the prior application; (iii) the specification and drawings filed in the continuation application contain no matter that would have been new matter in the prior application; and (iv) a copy of the executed oath or declaration filed in the prior application, showing the signature or an indication thereon that it was signed, is submitted for the continuation application. *See* 37 C.F.R. § 1.63(d)(1).

All of the requirements of 37 C.F.R. § 1.63(d)(1) are met with respect to the declaration that was submitted in the present application. First, the parent application, U.S. Patent Appl. No. 08/826,426, contained a declaration that meets the requirements of paragraphs (a) through (c) of 37 C.F.R. § 1.63. Second, the application was filed by the same inventors named in the parent. Third, the present specification and drawings contain no new matter. Fourth, a copy of the declaration that was filed in the parent application, containing the signatures of the inventors, was submitted with the present application at the time of filing.

Applicants also note that a copy of the originally filed Declaration and Power of Attorney was filed -- *along with the specification* -- on January 8, 1999. In other words, a copy of the specification was in fact attached to the Declaration. A photocopy of the date-stamped postcard indicating receipt by the USPTO of the specification and copy of the Declaration and Power of Attorney is submitted herewith as Exhibit A. Since the specification and the copy of the Declaration *were filed together*, the box next to the

statement indicating that "the specification is attached hereto unless the following box is checked" should *not* have been checked. Thus, the Examiner's rationale for objecting to the Declaration filed with the present application was in error.

II. Drawings

The Examiner noted the objections to the drawings raised by the Draftsperson and set forth on PTO Form 948. (*See* Paper No. 33, page 2.) Formal drawings that comply with 37 C.F.R. § 1.84 are submitted herewith. The objections to the drawings have therefore been fully accommodated and should be withdrawn.

III. Obviousness-Type Double Patenting

Claims 45-59, 61-71 and 81-82 were rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-10 and 13-16 of U.S. Patent No. 5,891,692.[1] (*See* Paper No. 33, page 3.) Applicants respectfully submit that the subject matter of claims 1-10 and 13-16 of U.S. Patent No. 5,891,692 would not have rendered obvious the invention as defined by claims 45-59, 61-71 and 81-82 of the present application, at the time the invention was made. Nevertheless, solely to expedite allowance of the application, Applicants submit herewith a terminal disclaimer over U.S. Patent No. 5,891,692. The rejection for obviousness type double patenting is therefore fully accommodated and should be withdrawn.

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[1]Applicants note that claims 45-47, 49-59, 61-71 and 81-82 are listed on the Office Action Summary Page (Form PTO-326) of Paper No. 33 as being allowed. (*See* Item No. 5.) The Examiner also included these claims among the allowed claims listed on page 7 of the present Office Action. In a telephone conversation with the undersigned on September 16, 2003, the Examiner indicated that the obviousness-type double patenting rejection of claims 45-59, 61-71 and 81-82 was intended, and the listing of claims 45-47, 49-59, 61-71 and 81-82 as being allowed was a mistake.

IV. Claim Rejection Under 35 U.S.C. § 112, First Paragraph

Claims 72-77, 80, 85-88 and 91 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. (*See* Paper No. 33, page 3.) Applicants respectfully traverse this rejection.

The rejection is based on the breadth of the claims. According to the Examiner, "the rejected claims are so broad in scope as to encompass cells comprising any modification in the expression of any gene that directly or *indirectly* increases the content of unsaturated fatty acids in the membrane of the cells." (Paper No. 33, page 5, emphasis in original.) Applicants submit that the subject matter encompassed by the claims is adequately described in the specification.

To satisfy the written description requirement of 35 USC § 112, first paragraph, Applicants must convey with reasonable clarity to those skilled in the art that, as of the effective filing date, Applicants were in possession of the invention. *See Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1560, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). As articulated by the Federal Circuit, "[t]he written description requirement does not require the applicant 'to describe exactly the subject matter claimed, [instead] the description must clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.'" *Union Oil Co. of Cal. v. Atlantic Richfield Co.*, 208 F.3d 989,997, 54 USPQ2d 1227, 1232 (Fed. Cir. 2000) (quoting *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989)). Since persons of ordinary skill in the art would have recognized that Applicants invented the subject matter encompassed by claims 72-77, 80, 85-88 and 91, the written description requirement is fully satisfied with respect to these claims.

Claims 72-77 and 80 are directed to competent *E. coli* possessing a membrane having an increased unsaturated fatty acid content relative to total fatty acid content, wherein the competent *E. coli* exhibits enhanced transformation ability relative to the transformation ability exhibited by the competent *E. coli* prior to increasing its unsaturated fatty acid content. Claims 85-88 and 91 are directed to competent *E. coli* having a membrane with an increased unsaturated fatty acid content, said increase caused by enhancing the expression of one or more genes that encode one or more gene products which increases said unsaturated fatty acid content.

The specification indicates that the invention includes *E. coli* having an increased unsaturated fatty acid content, where the increase is caused by a number of different factors. According to the specification:

> The method [of the invention] involves *modifying* or *mutating* a bacterium such that the fatty acid content of said bacterium is altered relative to an unmodified or unmutated bacterium. . . . Preferably, the amount of fatty acid is increased in the bacterium. This increase may be accomplished by various techniques, for example, *by adding one or more fatty acids to the bacterium* or by genetically modifying the bacterium. *Any type of genetic modification* may be used in accordance with the invention, including natural selection, artificial mutation, and genetic engineering. Such techniques are well known in the art.

(Specification at page 9, line 19, through page 10, line 2, emphasis added.) A person of ordinary skill in the art, in view of the foregoing description, would appreciate that the invention includes *E. coli* that have an increased unsaturated fatty acid content, and that the increase in unsaturated fatty acid content can be accomplished by any genetic or non-genetic methods.

In terms of genetic modifications, the specification indicates that the invention encompasses bacteria having an increased unsaturated fatty acid content, where the increase is caused by genetic modifications that *directly or indirectly* increase unsaturated fatty acid content. For instance, the specification notes that the fatty acid content can be increased by, *e.g.*, natural selection. (*See* specification at page 10, line 1.) Persons of ordinary skill in the art would appreciate that genetic alterations caused by natural selection include both mutations that act directly, and mutations that act indirectly to produce a particular phenotype (*e.g.*, increased unsaturated fatty acid content). As of the effective filing date of the application, the concept of indirect mutations (*e.g.*, increasing the expression of a gene by inactivating a repressor of that gene, *etc.*) was well established in the field of bacterial genetics. Thus, it would have been clear to a person of ordinary skill in the art, in view of the statement that "[a]ny type of genetic modification may be used in accordance with the invention," that the invention includes bacteria having an increased unsaturated fatty acid content, wherein the increase is caused by, *inter alia*, upregulating and/or downregulating genes that are *directly* involved in unsaturated fatty acid synthesis and/or genes that are *indirectly* involved in establishing or maintaining unsaturated fatty acid content in a cell.

The specification also provides working examples that demonstrate that Applicants had possession of the subject matter encompassed by claims 72-77, 80, 85-88 and 91. For instance, the specification describes *E. coli* strains that contain an extra copy of the *fabB* gene. Such *E. coli* are shown to possesses a membrane having an increased unsaturated fatty acid content and exhibit enhanced transformation ability after storage at a temperature of from about +4°C to about -20°C. (*See* specification at page 30, lines 13-21 (Example 10) and at page 46, line 5, through page 51, line 5 (Example 15).)

The specification also describes an *E. coli* strain (SB3499) which possesses a membrane having an increased unsaturated fatty acid content and that exhibits enhanced transformation ability after storage at a temperature of from about +4°C to about -20°C. The increased unsaturated fatty acid content for SB3499 was achieved by selection. (*See* specification at page 16, line 20, through page 19, line 5 (Examples 1-3) and at page 51, line 6, through page 54, line 13 (Example 16).)

In summary, persons of ordinary skill in the art, in view of the specification, would have recognized that the invention includes competent *E. coli* possessing a membrane having an increased unsaturated fatty acid content, wherein the increase in unsaturated fatty acid content is caused by any genetic or non-genetic method. Therefore, Applicants respectfully request that the rejection of claims 72-77, 80, 85-88 and 91 under 35 U.S.C. § 112, first paragraph, be reconsidered and withdrawn.

Conclusion

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants respectfully request that the Examiner reconsider the rejection under 35 U.S.C. § 112, first paragraph, and that it be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Reply is respectfully requested.

Respectfully submitted,

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